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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

JAMES BURGESS,)	
)	
Plaintiff,)	Civil Action No.:
v.)	
)	COMPLAINT
DAVOL INC., and C.R. BARD,)	
)	JURY TRIAL DEMANDED
Defendants.)	

Plaintiff, by and through his undersigned counsel, brings this Complaint for damages against Defendants and in support thereof states the following:

1. This is a device tort action brought on behalf of the above-named Plaintiff arising out of the failure of Defendants' hernia mesh product, the Bard Mesh PerFix Plug ("PerFix Plug"). As a result, Plaintiff JAMES BURGESS has suffered permanent injuries and significant pain and

suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiff respectfully seeks all damages to which he may be legally entitled.

STATEMENT OF PARTIES

2. Plaintiff is, and was, at all relevant times, a citizen and resident of Kentucky and the United States.

3. C.R. Bard, Inc. (“Bard”) is incorporated and based in New Jersey. Bard is a multinational marketer, promoter, seller, producer, manufacturer, and developer of medical devices. Bard controls the largest share of the hernia mesh market. Bard is the corporate parent/stockholder of Davol and participates in the manufacture and distribution of the PerFix Plug. Bard also manufactures and supplies Davol with material that forms part of the Bard Mesh PerFix Plug.

4. Davol, Inc. (“Davol”) is incorporated in Delaware and has its principal place of business in Rhode Island. Davol is a medical device company involved in the research, development, testing, manufacture, production, marketing, promotion and/or sale of medical devices, including an inguinal dart-shaped hernia mesh composed of polypropylene and known as the PerFix Plug.

5. Bard was at all times responsible for the actions of Davol, and exercised control over Davol’s functions specific to the oversight of and compliance with applicable safety standards relating to and including PerFix Plug sold in the United States. In such capacity, Bard committed or allowed to be committed tortious and wrongful acts, including the violation of numerous safety standards relating to device manufacturing, quality assurance/control, and conformance with design and manufacturing specifications. Bard’s misfeasance and malfeasance caused Plaintiff to suffer injury and damages.

6. Defendants are individually, jointly and severally liable to Plaintiff for damages suffered by Plaintiff arising from their design, manufacture, marketing, labeling, distribution, sale and placement of the defective PerFix Plug at issue in this suit. All acts were effectuated directly and indirectly through Defendant's respective agents, servants, employees and/or owners, acting within the course and scope of their representative agencies, services, employments and/or ownership.

7. Defendants are vicariously liable for the acts and/or omissions of their employees and/or agents, who were at all times relevant acting on Defendants' behalf and within the scope of their employment or agency with Defendants.

VENUE AND JURISDICTION

8. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(a), based on complete diversity of citizenship between Plaintiff and all Defendants. The amount in controversy exceeds \$75,000.00.

9. Venue is proper in this Court pursuant to 28 U.S.C. §1332(a)-(c) by virtue of the facts that (a) a substantial part of the acts or omissions giving rise to Plaintiff's claims occurred in this District; and (b) Defendants' products are sold to and consumed by individuals in the State of New Jersey. Defendants are thus subject to personal jurisdiction in this action and made "residents" of this judicial District.

10. Defendants have conducted, and continue to conduct, substantial business in the State of New Jersey and in this District; distribute PerFix Plug in this District; receive substantial compensation and profits from sales of PerFix Plug in this District; and make material omissions and misrepresentations and breaches of warranties in this District, so as to subject them to *in personam* jurisdiction in this District.

11. Defendants conducted business in the State of New Jersey through sales representatives conducting business in the State of New Jersey and because Defendants were engaged in testing, developing, manufacturing, labeling, marketing, distributing, promoting and/or selling, either directly or indirectly, and/or through third parties or related entities, PerFix Plug in New Jersey.

12. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, this Court has *in personam* jurisdiction over Defendants, because Defendants are present in the State of New Jersey, such that requiring an appearance does not offend traditional notions of fair and substantial justice.

FACTS COMMON TO ALL COUNTS

13. On or about January 6, 2012, Plaintiff JAMES BURGESS underwent right inguinal hernia repair by Dr. April Jackson, M.D. at Western Baptist Hospital in Paducah, Kentucky. An extra-large (4.1cm x 5.0cm) PerFix Plug, Ref. No. 0112780, Lot No. HUVJ0353 was implanted in Plaintiff during this repair.

14. Defendants manufactured, sold, and/or distributed the PerFix Plug to Plaintiff, through Plaintiff's doctors, to be used for treatment of hernia repair.

15. On or about February 2, 2017, Plaintiff JAMES BURGESS underwent recurrent right inguinal hernia repair with displaced old mesh and resection of old mesh performed.

16. Plaintiff continues to suffer chronic pain and possible recurrent hernia.

17. Defendants' PerFix Plug is a three-dimensional mesh product containing layers of polypropylene with a separate pre-shaped onlay polypropylene patch. Defendants market it as a mesh to be used in repairing hernias.

18. Defendants' PerFix Plug product contains several layers of polypropylene mesh. Despite Defendants' claims that this material is inert, a substantial body of scientific evidence shows that the mesh material is biologically incompatible with human tissue and promotes an immune response in a large subset of the population receiving the product. This immune response promotes degradation and contracture of the polypropylene mesh, as well as the surrounding tissue, and can contribute to the formation of severe adverse reactions to the mesh.

19. Upon information and belief, Defendants' numerous suppliers of various forms of polypropylene cautioned all users in their United States Material Safety Data Sheet that the polypropylene was not to be used for medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues.

20. Defendants failed to warn or notify doctors, regulatory agencies, and consumers of the severe and life-threatening risks associated with polypropylene.

21. PerFix Plug contains the following components:

- a. several layers of polypropylene constructed as a fluted outer layer with multiple inner layers; and
- b. one layer of pre-shaped polypropylene mesh with the option to be implanted as an onlay over the plug once implanted.

22. Defendants' PerFix Plug can contract up to 90% post-implantation.

23. In 2015, a study compared the recurrence rates for plug-and-patch hernia repair with standard flat mesh hernia repair utilizing the "Lichtenstein technique." The plug-and-patch had a recurrence rate of 9.9% compared to 5.6% for the standard flat mesh.¹

24. In 2018, the HerniaSurge Group published *International Guidelines for Groin Hernia Management*. The Guidelines were endorsed by the European Hernia Society, Americas

¹ Nienhuijs, S. and Rosman, C., *Long-term Outcome After Randomizing Prolene Hernia System, Mesh Plug Repair and Lichtenstein for Inguinal Hernia Repair*. *Hernia*, 19, pp. 77 – 81 (2015).

Hernia Society, Asia Pacific Hernia Society, Afro Middle East Hernia Society, Australasian Hernia Society, International Endo Hernia Society, and European Associated for Endoscopic Surgery and Other Interventional Techniques. The HerniaSurge Group's Guidelines note the following: "The incidence of erosion seems higher with plug versus flat mesh. It is suggested not to use plug repair techniques."

25. Defendants were responsible for the research, design, development, testing, manufacture, production, marketing, promotion, distribution and sale of PerFix Plug, including providing the warnings and instructions concerning the product.

26. Among the intended purposes for which Defendants designed, manufactured and sold PerFix Plug was use by surgeons for hernia repair surgeries. That is the purpose for which the PerFix Plug was implanted in Plaintiff.

27. Defendants represented to Plaintiff and Plaintiff's physicians that the PerFix Plug was a safe and effective product for hernia repair.

ESTOPPEL AND TOLLING OF STATUTE OF LIMITATIONS

28. Plaintiff asserts all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, class action tolling, delayed discovery, discovery rule, and fraudulent concealment.

29. Plaintiff pleads that the discovery rule should be applied to toll the running of the statute until Plaintiff knew, or through the exercise of reasonable care and diligence should have known, of facts indicating his injury, the cause of the injury, and the tortious nature of the wrongdoing that caused the injury.

30. Despite diligent investigation by Plaintiff into the cause of his injuries, including consultations with Plaintiff's medical providers, the nature of the injuries and damages, and their

relationship to the PerFix Plug was not discovered, and through reasonable care and diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiff's claims. Therefore, under appropriate application of the discovery rule, the action was filed well within the applicable statutory limitations period.

31. The running of the statute of limitations is tolled due to equitable tolling. Defendants are estopped from asserting a limitations defense due to their fraudulent concealment, through misrepresentations and omissions, from Plaintiff and Plaintiff's physicians of the true risks associated with the PerFix Plug. As a result of Defendants' fraudulent concealment, Plaintiff and his physicians were unaware, and could not have known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks alleged in this Complaint, and that those risks were the direct and proximate result of Defendants' wrongful acts and omissions.

COUNT I: STRICT LIABILITY – MANUFACTURING DEFECT

32. Plaintiff JAMES BURGESS incorporates by reference the allegations in all prior paragraphs.

33. Defendants expected and intended the PerFix Plug to reach users such as Plaintiff in the condition in which the product was sold.

34. The implantation of PerFix Plug in Plaintiff's body was medically reasonable, and was a type of use that Defendants intended and foresaw when they designed, manufactured and sold the product.

35. The PerFix Plug was defectively manufactured when it was implanted in Plaintiff's body.

36. Defendants' poor quality control and general non-compliance resulted in the non-conformance of the PerFix Plug implanted in Plaintiff. The implanted PerFix Plug did not conform to Defendants' intended manufacturing and design specifications.

37. Upon information and belief, Defendants utilized substandard and adulterated polypropylene in the PerFix Plug, which deviated from Defendants' material and supply specifications.

38. As a direct and proximate result of Defendants' defective manufacture of the PerFix Plug, Plaintiff suffered injuries and damages as summarized in this Complaint.

COUNT II: STRICT LIABILITY – DESIGN DEFECT

39. Plaintiff JAMES BURGESS incorporates by reference the allegations in all prior paragraphs.

40. Defendants' PerFix Plug was defectively designed and/or manufactured and was not reasonably safe for its intended use in hernia repair. The risks of the design outweighed any potential benefits associated with the design. As a result of the defective design and/or manufacture of the PerFix Plug, there was an unreasonable risk of severe adverse reactions to the mesh or mesh components including: chronic pain; recurrence of hernia; foreign body response; rejection; infection; scarification; improper wound healing; excessive and chronic inflammation; allergic reaction; adhesions to internal organs; erosion; abscess; fistula formation; granulomatous response; seroma formation; nerve damage; tissue damage and/or death; and other complications.

41. The PerFix Plug includes a tapered design, which promotes mesh migration in the direction of the taper.

42. The three-dimensional design of the PerFix Plug promotes mesh contracture or mesh "wadding," "balling," or "knuckling" up.

43. Mesh porosity impacts tissue ingrowth and the inflammatory response. Large-pore meshes have fewer complications than small-pore meshes. A pore size greater than 1.5 mm defines “large-pore-size.” Complications continue to decrease as mesh pore size increases beyond 1.5 mm. A small-pore-size decreases tissue incorporation, increases inflammation, and results in a fibrotic reaction. The PerFix Plug has a mesh pore size of less than 0.5 mm.

44. Large-pore flat meshes have a lower risk of mesh-related complications compared to small-pore three-dimensional meshes like Defendants’ PerFix Plug.

45. Shrinkage and stiffness of flexible meshes is affected by scar tissue. The PerFix Plug has smaller inter-filament distances and pores, which increases the risk of bridging by scar tissue.

46. Plugs, when compared with flat meshes, have a higher risk of extensive fibrosis and are more likely to stimulate an intense inflammatory reaction, thereby resulting in nonconforming biomechanical properties.

47. Hernia repair with the PerFix Plug necessitates entering both the anterior and posterior compartments, which is not necessary when repairing a hernia with a standard flat mesh. Entering both the anterior and posterior compartments increases scarring, making a subsequent repair for hernia recurrence more difficult.

48. The PerFix Plug has multiple layers of polypropylene, increasing the mesh surface area and foreign body load, which in turn increases the inflammatory and foreign body response.

49. The polypropylene weave of the PerFix Plug produces very small interstices that allow bacteria to enter and hide from the host defenses designed to eliminate them. The bacteria can secrete an encasing slime (biofilm) that further serves to protect them from destruction by white blood cells and macrophages.

50. Observation of mesh under a scanning electron microscope reveals that very small interstices exist between the PerFix Plug mesh fibrils, which are too small for a macrophage to enter to destroy incubating bacteria. Some bacteria are capable of degrading polypropylene.

51. These manufacturing and design defects associated with the PerFix Plug were directly and proximately related to the injuries Plaintiff JAMES BURGESS suffered.

52. Neither Plaintiff nor Plaintiff's implanting physician was adequately warned or informed by Defendants of the defective and dangerous nature of PerFix Plug. Moreover, neither Plaintiff nor his implanting physician was adequately warned or informed by Defendants of the risks associated with the PerFix Plug.

53. The PerFix Plug implanted in Plaintiff JAMES BURGESS failed to reasonably perform as intended. The PerFix Plug caused serious injury and had to be partially resected via invasive surgery, and necessitated additional invasive surgery to repair the hernia that the PerFix Plug was initially implanted to treat.

54. As described above, there was an unreasonable risk that the PerFix Plug, which was defectively designed, would not perform safely and effectively for the purposes for which it was intended. Defendants failed to design against such dangers, and failed to provide adequate warnings and instructions concerning these risks.

55. Defendants expected and intended the PerFix Plug to reach users such as Plaintiff in the condition in which the PerFix Plug was sold.

56. The implantation of the PerFix Plug in Plaintiff's body was medically reasonable, and was a type of use that Defendants intended and foresaw when they designed, manufactured and sold the product.

57. The risks of the PerFix Plug significantly outweigh any benefits that Defendants contend could be associated with it. The dart-like design—which is not used in any other hernia mesh product sold in the United States—promotes mesh migration and incites an intense inflammatory response, leading to encapsulation, deformation, scarification and contraction, erosion, rejection and further migration.

58. The polypropylene mesh utilized to manufacture the PerFix Plug was in itself dangerous and defective, particularly when used in the manner intended by Defendants in the PerFix Plug. The particular polypropylene material used in the PerFix Plug was substandard, adulterated and non-medical grade, and was unreasonably subject to oxidative degradation within the body. When implanted as intended, adjacent internal organs, structures, nerves, arteries, and vessels, polypropylene mesh is unreasonably susceptible to adhesion formation, nerve entrapment, spermatic cord obliteration, organ perforation or erosion, fistula formation and bowel strangulation or hernia incarceration, and other injuries.

59. The appropriate treatment for complications associated with the PerFix Plug involves additional invasive surgery to remove the mesh from the body, thus eliminating any purported benefit that the mesh was intended to provide to a patient.

60. When the PerFix Plug was implanted in Plaintiff, there were safer feasible alternative designs for hernia mesh products, including but not limited to, a flat, non-coated, single-layer, porous mesh.

61. The PerFix Plug product cost significantly more than competitive products because of its unique dart shape—even though the dart shape provided no benefit to consumers, and increased the risks to patients implanted with these devices.

62. The PerFix Plug implanted in Plaintiff JAMES BURGESS failed to reasonably perform as intended. It had to be surgically removed, necessitating further invasive surgery to repair the very issue that the product was intended to repair, and thus providing no benefit to him.

63. As a direct and proximate result of the defective and unreasonably dangerous condition of the product, Plaintiff suffered injuries and damages as summarized in this Complaint.

COUNT III: STRICT LIABILITY – FAILURE TO WARN

64. Plaintiff incorporates by reference the allegations in all prior paragraphs.

65. When the PerFix Plug was implanted in Plaintiff's body, the warnings and instructions Defendants provided were inadequate and defective. As described above, there was an unreasonable risk that the product would not perform safely and effectively for the purposes for which it was intended, and Defendants failed to design and/or manufacture against such dangers, and failed to provide adequate warnings and instructions concerning these risks.

66. Defendants expected and intended the PerFix Plug product to reach users such as Plaintiff JAMES BURGESS in the condition in which the product was sold.

67. Plaintiff and his physicians were unaware of the defects and dangers of the PerFix Plug, and were unaware of the frequency, severity and duration of the risks associated with the product.

68. The Instructions for Use Defendants provided with the PerFix Plug are silent on the fact of the PerFix Plug's propensity to migrate post-implantation in the direction of the taper. Defendants provided no warning to physicians about the risks or increased risks specifically associated with the unique dart-like design of the PerFix Plug.

69. The Instructions for Use for the PerFix Plug also failed to adequately warn Plaintiff's physicians of numerous risks that Defendants knew or should have known were

associated with the PerFix Plug, including: risks of the product's immunologic response, pain, encapsulation, rejection, migration, scarification, contraction, adhesion to internal structures or organs, erosion and migration through adjacent tissue and viscera, bowel obstruction, or hernia incarceration or strangulation.

70. Defendants failed to adequately warn implanting surgeons of the significant risk of complications associated with mesh migration if the PerFix Plug is implanted in the abdomen to repair a ventral hernia.

71. Defendants failed as well to adequately warn Plaintiff or Plaintiff's physicians about the necessity for invasive surgical intervention in the event of complications with the PerFix Plug, or train the physicians on the proper treatment of such complications when they occurred.

72. Defendants failed to adequately warn Plaintiff or his physicians that: the surgical removal of the PerFix Plug in the event of complications would leave the hernia unrepaired; the resulting hernia would be much larger than the original; and further, more complicated medical treatment to attempt to repair the same hernia would be necessary.

73. Defendants represented to physicians, including Plaintiff's physician, that the tapered design would prevent or reduce recurrences and pain. They expressly intended for the PerFix Plug to be implanted near numerous large nerves and organs, and marketed and promoted the PerFix Plug for that purpose. Defendants failed to warn physicians that the PerFix Plug would contract over time, increasing the rates of recurrence and the ability of the PerFix Plug to migrate.

74. With respect to the complications listed in their warnings, Defendants provided no information or warning regarding the frequency, severity and duration of those complications, although the complications associated with the PerFix Plug were more frequent, more severe and longer lasting than those in safer feasible alternative hernia repair treatments.

75. If Plaintiff and/or Plaintiff's physicians had been properly warned of the defects and dangers of the PerFix Plug, and of the frequency, severity and duration of the risks associated with the product, Plaintiff would not have consented to allow the PerFix Plug to be implanted, and Plaintiff's physicians would not have implanted the product in Plaintiff.

76. As a direct and proximate result of the inadequate and defective warnings and instructions, Plaintiff suffered injuries and damages as summarized in this Complaint.

COUNT IV: NEGLIGENCE

77. Plaintiffs incorporate by reference the allegations in all prior Paragraphs.

78. Although Defendants had a duty to use reasonable care in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, and preparing written instructions and warnings for the PerFix Plug, they failed to do so.

79. Defendants knew, or in the exercise of reasonable care should have known, that the PerFix Plug was defectively and unreasonably designed and/or manufactured, and was unreasonably dangerous and likely to injure patients in whom the product was implanted. Defendants knew or should have known that Plaintiff and Plaintiff's physicians were unaware of the dangers and defects inherent in the PerFix Plug.

80. Defendants knew or should have known that the Material Data Safety Sheet for the polypropylene used to manufacture their PerFix Plug prohibited permanently implanting the polypropylene into the human body.

81. Defendants utilized non-medical grade polypropylene.

82. Defendants knew or should have known that polypropylene is not inert and would degrade, flake, chip, and disperse throughout the body once implanted.

83. Defendants knew or should have known that polypropylene incites a severe inflammatory response once implanted, and continues to incite a severe inflammatory response indefinitely or until removed.

84. Defendants knew or should have known that every piece of polypropylene that flakes off and migrates throughout the body also incites its own chronic inflammatory response wherever it embeds.

85. Defendants knew or should have known that the tapered design of the PerFix Plug would promote mesh migration.

86. Defendants knew or should have known of the significant risk of complications if the PerFix Plug is implanted into the abdomen to repair a ventral hernia. Nonetheless, Defendants marketed the PerFix Plug off-label as being safe and effective for ventral and abdominal incisional hernia repair.

87. Defendants knew or should have known that small pore size and multiple layers of the PerFix Plug would increase mesh surface area and foreign body load, which in turn would increase the inflammatory and foreign body response.

88. As a direct and proximate result of Defendants' negligence in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, and preparing written instructions and warnings for PerFix Plug, Plaintiff suffered injuries and damages as summarized in this Complaint.

COUNT V: BREACH OF EXPRESS WARRANTY

89. Plaintiff incorporates by reference the allegations in all prior paragraphs.

90. At all material times, Defendants manufactured, marketed, sold, distributed and otherwise placed in to the stream of commerce the PerFix Plug.

91. In advertising, marketing and otherwise promoting the PerFix Plug to physicians, hospitals and other healthcare providers, Defendants expressly warranted that their product was safe for use and reasonably fit for its intended purposes. In advertising, marketing and otherwise promoting the PerFix Plug, Defendants intended that physicians, hospitals and other healthcare providers rely upon their representations regarding safety and fitness, to induce them to implant the PerFix Plug in their patients.

92. With respect to Plaintiff JAMES BURGESS, Defendants intended that the PerFix Plug be implanted by his treating surgeon in a reasonable and foreseeable manner, and in accordance with the instructions for use and product specifications provided by Defendants. Plaintiff was in privity with Defendants.

93. Defendants expressly warranted the following to physicians, hospitals, other healthcare providers and the general public, including Plaintiff JAMES BURGESS: the PerFix Plug was safe and fit for use by consumers; it was of merchantable quality; its risks, side effects and potential complications were minimal and comparable to other hernia mesh products; it was adequately researched and tested; and it was fit for its intended use. Plaintiff and Plaintiff's physicians and healthcare providers reasonably relied upon Defendants' express representations and warranties, and consequently, Plaintiff was implanted with Defendants' product.

94. Defendants expressly warranted to physicians, hospitals, other healthcare providers and the general public, including Plaintiff, that the PerFix Plug safe and fit for use for the repair of both inguinal and abdominal hernia.

95. Defendants represented that the PerFix Plug would prevent or minimize hernia recurrence and pain, and facilitate incorporation of the mesh into the body, but it did not. Instead, the PerFix Plug caused an intense systemic inflammatory and chronic foreign body response,

resulting in an adverse tissue reaction including damage to surrounding tissue in the form of sclerotic, granulomatous and/or fibrotic tissue and improper or delayed healing.

96. Defendants breached these express warranties because the PerFix Plug implanted in Plaintiff was unreasonably dangerous, defective, and not as Defendants had represented.

97. Defendants breached express representations and warranties to Plaintiff, as well as his physicians and healthcare providers, with respect to the PerFix Plug, by representing the following:

- a. through labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions, among other methods, that their product was safe; but they fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the PerFix Plug.
- b. the PerFix Plug was as safe and/or safer than other alternative procedures and devices on the market; but they fraudulently concealed information demonstrating that PerFix Plug was not safer than alternative therapies and products available on the market; and
- c. the PerFix Plug was more efficacious than other alternative procedures, therapies and/or devices; but they fraudulently concealed information regarding the true efficacy of the product.

98. Defendants' breach of their express warranties resulted in the implantation of an unreasonably dangerous and defective product into Plaintiff, placing his health and safety in jeopardy.

99. When Defendants made such express warranties, they knew or should have known that their PerFix Plug does not conform to the express warranties. Defendants' acts were motivated by financial gain, while the adverse consequences of their conduct were outrageous, fraudulent, oppressive, done with malice or gross negligence and evidenced reckless indifference to Plaintiff's rights, health and safety, so as to warrant the imposition of punitive damages.

COUNT VI: BREACH OF IMPLIED WARRANTY

100. Plaintiff incorporates by reference the allegations in all prior paragraphs.

101. At all material times, Defendants manufactured, distributed, advertised, promoted, and sold the PerFix Plug.

102. At all material times, Defendants intended that the product be implanted for the purposes and in the manner that Plaintiff and/or his implanting physicians in fact used them; and Defendants impliedly warranted each PerFix Plug and its component parts to be of merchantable quality, safe and fit for such use, and adequately tested.

103. Defendants were aware that consumers, including Plaintiff or Plaintiff's physicians, would implant their PerFix Plug in the manner directed by the instructions for use. Thus, Plaintiff was a foreseeable user of the product.

104. Plaintiff and/or Plaintiff's physicians were at all material times in privity with Defendants.

105. The PerFix Plug was expected to reach, and did in fact reach consumers, including Plaintiff or Plaintiff's physicians, without substantial change in the condition in which Defendants manufactured and sold it.

106. Defendants breached various implied warranties with respect to the PerFix Plug, including the following to Plaintiff and Plaintiff's physicians and healthcare providers:

- a. Defendants represented through labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the PerFix Plug was safe; but fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the product;
- b. Defendants represented that the PerFix Plug was safe, and/or safer than other alternative procedures and devices; but fraudulently concealed information demonstrating that the product was no safer than alternatives available on the market; and

c. Defendants represented that the PerFix Plug was more efficacious than other alternative procedures and/or devices; but fraudulently concealed information regarding the true efficacy of the PerFix Plug.

107. In reliance upon Defendants' implied warranties, Plaintiff individually and/or by and through his physician, used the PerFix Plug as prescribed and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

108. Defendants breached their implied warranty to Plaintiff in that the PerFix Plug was not of merchantable quality, safe and fit for its intended use, or adequately tested.

109. As a direct and proximate result of Defendants' breaches of implied warranties, Plaintiff was caused to suffer, and did suffer, severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including obligations for medical services and expenses, impairment of personal relationships, and other damages.

**COUNT VII: VIOLATION OF FEDERAL & STATE
CONSUMER PROTECTION LAWS**

110. Plaintiff incorporates by reference the allegations in all prior paragraphs.

111. Plaintiff purchased and used the PerFix Plug primarily for personal use, and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

112. Had Defendants not engaged in the deceptive conduct described in this Complaint, Plaintiff would not have purchased and/or paid for the PerFix Plug, and would not have incurred related medical costs and injury.

113. Defendants engaged in wrongful conduct, while at the same time obtaining, under false pretenses, moneys from Plaintiff for the PerFix Plug, which would not have been paid had Defendants not engaged in unfair and deceptive conduct.

114. Unfair methods of competition or deceptive acts or practices that were proscribed by law, include the following:

- a. representing that goods or services have characteristics, ingredients, uses, benefits or qualities that they do not have;
- b. advertising goods or services with the intent not to sell them as advertised; and,
- c. engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

115. Plaintiff was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create demand for and sell the PerFix Plug. Each aspect of Defendants' conduct combined to artificially create sales of the product.

116. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of the PerFix Plug.

117. Had Defendants not engaged in the deceptive conduct described above, Plaintiff would not have purchased and/or paid for the PerFix Plug, and would not have incurred related medical costs.

118. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiff, constituted unfair and deceptive acts and trade practices in violation of the federal and state consumer protection statutes listed below.

119. Defendants' actions constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of federal and state consumer protection statutes listed below.

120. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or false advertising, or have made false representations in violation of:

- 15 U.S.C. §§ 2301-2312 (1982)
- N.J. Stat. Ann §§ 56:8-1, et seq.
- R.I. Gen. Laws §§ 6-13.1, et. seq.

121. Under the statutes listed above Defendants are the suppliers, manufacturers, advertisers, and sellers subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

122. Defendants violated the statutes enacted to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the PerFix Plug was fit to be used for the purpose for which it was intended, when in fact it was defective and dangerous, and by other acts alleged in this Complaint. These representations were made in marketing and promotional materials.

123. Defendants' actions and omissions are uncured or incurable deceptive acts under the consumer protection laws.

124. Defendants had actual knowledge of the defective and dangerous condition of the PerFix Plug and failed to take any action to cure such defective and dangerous conditions.

125. Plaintiff and the medical community relied upon Defendants' misrepresentations and omissions in determining which product and/or procedure to undergo and/or perform (if any).

126. Defendants' deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, constituted unfair and deceptive acts and practices.

127. By reason of the unlawful acts in which Defendants engaged, and as a direct and proximate result of those acts, Plaintiff has suffered ascertainable losses and damages.

128. As a direct and proximate result of Defendants' violations of the consumer protection laws, Plaintiff has sustained economic losses and other damages and is entitled to statutory and compensatory damages in an amount to be proven at trial.

COUNT VIII: GROSS NEGLIGENCE

129. Plaintiff incorporates by reference the allegations in all prior paragraphs.

130. Defendants' acts or omissions were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff for which the law would allow, and which Plaintiff will seek at the appropriate time under governing law, the imposition of exemplary damages. Defendants' conduct, including the failure to comply with applicable federal and state standards was specifically intended to cause substantial injury to Plaintiff; or when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved. Nevertheless, they proceeded with conscious indifference to the rights, safety, or welfare of others; or included a material representation that was false, with knowledge of its falsity or with reckless disregard as to its truth, and as a positive assertion, with the intent that the representation is acted on by Plaintiff.

131. Plaintiff JAMES BURGESS relied on the representation and suffered injury as a proximate result of this reliance.

132. Plaintiff therefore will seek to assert claims for exemplary damages at the appropriate time under governing law, in an amount within the jurisdictional limits of the Court.

133. Defendants' acts and omissions, whether taken singularly or in combination with others, constitute gross negligence that proximately caused the injuries to Plaintiff. In that regard,

Plaintiff will seek exemplary damages in an amount that would punish Defendants for their misconduct and which would deter other manufacturers from engaging in such misconduct in the future.

COUNT IX: UNJUST ENRICHMENT

134. Plaintiff incorporates by reference the allegations in all prior paragraphs.

135. Defendants are and at all material times were the manufacturers, sellers, and/or suppliers of the PerFix Plug.

136. Plaintiff paid for Defendants' product for the purpose of treatment for hernia repair and/or a soft tissue injury or other similar condition.

137. Defendants have accepted payment by Plaintiff and others on Plaintiff's behalf for the purchase of the PerFix Plug.

138. Plaintiff has not received the safe and effective medical device for which he has paid.

139. It would be inequitable for Defendants to keep this money, because Plaintiff did not in fact receive a safe and effective medical device.

COUNT X: NEGLIGENCE INFLICTION OF EMOTIONAL DISTRESS

140. Plaintiff incorporates by reference the allegations in all prior paragraphs.

141. Defendants carelessly and negligently manufactured, designed, developed, tested, labeled, marketed and sold the PerFix Plug to Plaintiff.

142. Defendants carelessly and negligently concealed the harmful effects of their product from Plaintiff, individually and/or Plaintiff's physician, on multiple occasions. They continue to do so to this day.

143. Defendants carelessly and negligently misrepresented the quality, safety and efficacy of the PerFix Plug to Plaintiff, individually and/or Plaintiff's physician, on multiple occasions. They continue to do so to this day.

144. Plaintiff was directly impacted by Defendants' carelessness and negligence, in that he has sustained and will continue to sustain emotional distress, severe physical injuries, economic losses, and other damages as a direct result of the decision to purchase the PerFix Plug sold and distributed by Defendants.

145. Defendants continued to carelessly and negligently misrepresent the quality, safety, efficacy, dangers and contraindications of the PerFix Plug to Plaintiff, individually and/or Plaintiff's physician, after Plaintiff sustained emotional distress, severe physical injuries, and economic loss.

146. Defendants continued to carelessly and negligently misrepresent the quality, safety, efficacy, dangers and contraindications of the PerFix Plug to Plaintiff, individually and/or Plaintiff's physician, knowing that doing so would cause him to suffer additional and continued emotional distress, severe physical injuries, and economic loss.

147. As a proximate result of the Defendants' acts or omissions, Plaintiff has been injured, sustained severe and permanent pain, suffering, anxiety, depression, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

COUNT XI: FRAUDULENT CONCEALMENT

148. Plaintiff incorporates by reference the allegations in all prior paragraphs.

149. At all material times, Defendants knew or should have known that the PerFix Plug caused large numbers of complications. Moreover, they also knew or should have known the following: the surgical technique and training of implanting physicians was not the cause of the

adverse events associated with these devices; the safety and efficacy of its PerFix Plug had not been proven with respect to, among other things, the product, its components, its performance, and its method of insertion; the PerFix Plug was not safe and effective. But Defendants continued to represent that the PerFix Plug was safe and effective.

150. Despite what Defendants knew or should have known about the lack of safety and efficacy of the PerFix Plug, they failed to disclose this information to Plaintiff JAMES BURGESS, to Plaintiff's physicians, and to the public at large.

151. At all material times, Defendants had the duty and obligation to disclose to Plaintiff and Plaintiff's physicians the true facts concerning the PerFix Plug: that it was dangerous and defective, lacking efficacy for its purported use and lacking safety in normal use, and the likelihood of its causing serious consequences to users, including permanent and debilitating injuries. Defendants concealed these material facts before Plaintiff was implanted with their product.

152. Defendants were under a duty to Plaintiff to disclose and warn of the defective nature of the PerFix Plug because:

- a. Defendants were in a superior position to know the true quality, safety, and efficacy of the PerFix Plug;
- b. Defendants knowingly made false claims in documents and marketing materials about the safety and quality of the PerFix Plug; and
- c. Defendants fraudulently and affirmatively concealed the defective nature of the PerFix Plug from Plaintiff.

153. The facts concealed and/or not disclosed by Defendants to Plaintiff and his physician were material facts that a reasonable person would have considered to be important in deciding whether to purchase and/or use the PerFix Plug.

154. At all material times, Defendants willfully, intentionally, and maliciously concealed facts as set forth above from Plaintiff and his physician, with the intent to defraud.

155. Defendants intentionally concealed and/or failed to disclose the true defective nature of the PerFix Plug so that Plaintiff would request and purchase the product, and his healthcare providers would dispense, prescribe, and recommend the PerFix Plug; and Plaintiff justifiably acted or relied upon the concealed and/or non-disclosed facts to his detriment.

156. At all material times, neither Plaintiff nor Plaintiff's physician was aware of the facts set forth above. Had they been aware of the facts, they would not have acted as they did, *i.e.*, would not have reasonably relied upon the representations of safety and efficacy and utilized the PerFix Plug in their treatment. Defendants' failure to disclose this information was a substantial factor in Plaintiff's physicians selecting Defendants' PerFix Plug. The failure to disclose also resulted in the provision of incorrect and incomplete information to Plaintiff, as a patient.

157. As a direct and proximate result of Defendants' conduct, Plaintiff was injured.

COUNT XII: CONSTRUCTIVE FRAUD

158. Plaintiff incorporates by reference the allegations in all prior paragraphs.

159. Defendants are in a unique position to know about the quality, safety, and efficacy of the PerFix Plug. That knowledge is not possessed by Plaintiff or his physician. Defendants thereby hold a position of superiority over Plaintiff and Plaintiff's physician.

160. Despite their unique and superior knowledge regarding the defective nature of the PerFix Plug, Defendants continue to suppress, conceal, omit, and/or misrepresent information to Plaintiff, the medical community, and the public, concerning the severity and frequency of risks and dangerous inherent in the intended use of the product, as compared to other products and forms of treatment.

161. Defendants have concealed and suppressed material information that would reveal that the PerFix Plug had a higher risk of adverse effects, in addition to, and exceeding those

associated with alternative procedures and available devices. Instead, Defendants have misrepresented the safety and efficacy of the PerFix Plug.

162. Upon information and belief, Defendants' misrepresentation are designed to induce physicians to prescribe, dispense, recommend, and/or purchase the PerFix Plug. Plaintiff and the medical community have relied upon Defendants' misrepresentations.

163. Defendants took unconscionable advantage of their dominant position of knowledge with regard to Plaintiff and Plaintiff's healthcare providers, and engaged in constructive fraud in their relationship with Plaintiff and Plaintiff's medical providers. Plaintiff reasonably relied on Defendants' representations.

164. As a proximate cause of Defendants' acts and omissions, Plaintiff has been injured and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, economic damages.

COUNT XIII: NEGLIGENT MISREPRESENTATION

165. Plaintiff incorporates by reference the allegations in all prior paragraphs.

166. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff, and the public, that the PerFix Plug had not been adequately tested and found to be a safe and effective treatment. Defendants' representations were in fact false.

167. Defendants failed to exercise ordinary care in the representations concerning the PerFix Plug while they were involved in its manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because Defendants negligently misrepresented, or concealed, the PerFix Plug's high risk of unreasonable and dangerous adverse side effects.

168. Defendants breached their duty in representing to Plaintiff, Plaintiff's physicians, and the medical community, that the PerFix Plug had no serious side effects different from those of other similar products and/or procedures.

169. As a foreseeable, direct, and proximate result of Defendants' negligent misrepresentation, they knew or should have known that the PerFix Plug had been insufficiently tested, or had not been tested at all. As well, they knew or should have known that the product lacked adequate and accurate warnings, creating a high risk—or higher than acceptable or reported and represented risk—of adverse side effects. Those included pain, graft rejection, graft migration, organ damage, complex seroma, fistula, sinus tract formation, delayed wound closure, infection, sepsis, and death.

170. As a direct and proximate result of Defendants' acts and omissions, Plaintiff JAMES BURGESS has been injured and sustained severe pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, economic damages.

COUNT XIV: PUNITIVE OR ENHANCED COMPENSATORY DAMAGES

171. Plaintiff incorporates the allegations in all prior paragraphs.

172. Defendants failed to adequately test and study the PerFix Plug to determine and ensure that the product was safe and effective before releasing the product for sale for permanent human implantation; and Defendants continued to manufacture and sell the product after having obtained knowledge and information that it was defective and unreasonably unsafe.

173. Although Defendants have other hernia repair mesh devices that do not present the same risks as the PerFix Plug, they developed, designed and sold the PerFix Plug, and continue to do so, because the PerFix Plug has a significantly higher profit margin than other hernia repair products. Defendants were aware of the probable consequences of implantation of the dangerous

and defective PerFix Plug, including the risk of failure and serious injury, such as suffered by Plaintiff.

174. At all material times, Defendants knew or should have known that the PerFix Plug was inherently more dangerous with respect to the following risks: migration, foreign body response, allergic reactions, rejection, infection, failure, erosion, pain and suffering, organ perforation, dense adhesions, loss of life's enjoyment, remedial surgeries and treatments in an effort to cure the conditions proximately related to the product's use, as well as other permanent and lasting severe and personal injuries.

175. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiff, concerning the safety and efficacy of the PerFix Plug, thus depriving Plaintiff and his implanting physicians of vitally necessary information necessary to make a fully informed decision about whether to use the product.

176. At all material times, Defendants knew and recklessly and/or intentionally disregarded the fact that the PerFix Plug can cause debilitating and potentially life-threatening side effects with greater frequency than safer alternative methods, products, procedures, and/or treatment. But they recklessly failed to advise the medical community and the general public, including Plaintiff, of the risks and side effects.

177. At all material times, Defendants intentionally misstated and misrepresented data, and continue to misrepresent data, so as to minimize the perceived risk of injuries and the rate of complications associated with PerFix Plug.

178. Notwithstanding the foregoing and the growing body of knowledge and information regarding the true and defective nature of the PerFix Plug's increased risk of side

effects and serious complications, Defendants continue to aggressively market the product to the medical community and to consumers without disclosing the true risk of such complications.

179. When Plaintiff JAMES BURGESS was implanted with the PerFix Plug and since then, Defendants have known that the PerFix Plug was defective and unreasonably dangerous. Nonetheless, they have continued to manufacture, produce, assemble, market, distribute, and sell the product so as to maximize sales and profits at the expense of the health and safety of the public, in a conscious, reckless and/or intentional disregard of the likely and foreseeable harm caused by the PerFix Plug to the public, including Plaintiff.

180. At all material times, Defendants have concealed and/or failed to disclose to the public the serious risks and the potential complications associated with the PerFix Plug, to ensure continued and increased sales and profits, to the detriment of the public, including Plaintiff.

181. Defendants' acts and omissions are of such character and nature so as to entitle Plaintiff to an award of punitive damages in accordance with applicable statutory and common law. Defendants' conduct shows willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care, which raise the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants, individually, jointly, and severally; and requests compensatory damages, punitive damages or enhanced compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

PRAYER FOR RELIEF

Plaintiff JAMES BURGESS demands judgment against Defendants, individually, jointly and severally, and prays for the following relief in accordance with applicable law and equity:

- i. Compensatory damages to Plaintiff for past, present, and future damages, including but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiff, permanent impairment, mental pain and suffering, loss of enjoyment of life, health and medical care costs, economic damages, together with interest and costs as provided by law;
- ii. restitution and disgorgement of profits;
- iii. punitive or enhanced compensatory damages;
- iv. reasonable attorneys' fees as provided by law;
- v. costs of these proceedings, including past and future costs of suit;
- vi. all ascertainable economic damages;
- vii. prejudgment interest on all damages as allowed by law; and
- viii. such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff JAMES BURGESS hereby demands a trial by jury on all issues so triable.

Respectfully submitted,

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Dated: January 31, 2018

/s JOSHUA S. KINCANNON

JOSHUA S. KINCANNON, ESQ.